

Docket No. ORT-1510

IN THE STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. McDonnell, Larry E. Weaner and Sui Po

Zhanq

Serial No.: 09/973,378

Art Unit:

Filed

: October 9, 2001

Examiner:

For

: NOVEL LABELED RESINIFERATIOXIN DERIVATIVES

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, D.C. 20231 on

February 11, 2002
(Date of Deposit)

John W. Harbour

(Name of applicant, assignee, or Registered Representative)

February 11, 2002

(Date of Signature)

Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with \square the first or Second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in \$1.17(p). In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is

accompanied by one of:

<pre>Statement in Accordance with §1.97(e)</pre>	
(attached); or	
Please charge Deposit Account No. 10-0750/ /	
the fee of $$180.00$ as set forth in $$1.17(p)$.	
In accordance with §1.97(d), this Information	
Disclosure Statement is being filed after the mailing date of	
either a Final Action under §1.113 or a Notice of Allowance	
under §1.311 but before the payment of the Issue Fee.	
Applicant(s) hereby petition(s) for consideration of this	
Information Disclosure Statement. Included are: Statement in	
Accordance with §1.97(e) as set forth below and the fee of	
\$180.00 as set forth in §1.17(p).	
M Garies of each of the references listed on the	
Copies of each of the references listed on the	
attached Form PTO-1449 are enclosed herewith.	
Copies of references listed on the attached Form PTO-	
1449 are enclosed herewith EXCEPT THAT:	
In view of the voluminous nature of references	
[list as appropriate], and the likelihood that	
these references are available to the Examiner,	
copies are not enclosed herewith.	
If any of the foregoing publications are not	
available to the Examiner, Applicant will	
endeavor to supply copies at the Examiner's	
request.	
igotimes There are no listed references which are not in the	
English language.	

at 5

The relevance of those listed references which are not in the English language is as follows: Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D. Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D. Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1510/JWH. This form is submitted in triplicate. Respectfully submitted, John W. Harbour Req. No. 31365 Attorney for Applicants Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2169

DATED: February 11, 2002



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control numb

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 2

a collection of information unless it displays a valid OMB control number.		
Application Number	09/973,378	
Filing Date	October 9, 2001	
First Named Inventor	McDonnell et al	
Group Art Unit		
Examiner Name		
Attorney Docket Number	ORT-1510	

U.S. PATENT DOCUMENTS						
U.S. Patent Document Name of Patentee or Applicant Date of Publication						Pages Columns Lines
Examiner Initials	Cite No.1	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	of Cited Document mm-dd-yyyy	cument where relevant passages
		<u> </u>				

FOREIGN PATENT DOCUMENTS Date of Publication Pages, Columns, Lines, Foreign Patent Document of Cited Document where relevant Name of Patentee or passages or relevant T⁶ Examiner Cite mm-dd-yyyy Applicant of Cited Document figures appear Initials Office³ Number⁴ KindCode⁵ No.1 The Uniited States of America 05-22-1998 wo 98/20867 represented by The Secretary, Department of Health and Human Services The Regents of the University of 02-25-1999 9/09140

Examiner	Date	
	Considered	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Re

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 2 of 2

a collection of information unless it displays a	valid OMB control number.
Application Number	09/973,378
Filing Date	October 9, 2001
First Named Inventor	McDonnell et al
Group Art Unit	
Examiner Name	
Attorney Docket Number	ORT-1510

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
	-/	S. BEVAN AND J. SZOLCSANYI, Sensory neuron-specific actions of capsaicin: mechanisms and applications, Trends Pharmacol Sci, Aug 1990 Vol. 11 pp. 330-333.	
	-	J. SZOLCSANYI, Capsaicin-sensitive sensory nerve terminals with local and systemic efferent functions: facts and scopes of an unorthodox neuroregulatory mechanism, Progress in Brain Research, 1996, Vol 113, pp 343-359	
	=	SZOLCSANYI ET AL., Resiniferatoxin: An Ultrapotent Neurotoxin of Capsaicin-sensitive Primary Afferent Neurons, Annals of the New York Academy of Sciences, 1991 Vol 632, pp 473-475.	
	7	VERONESI ET AL, Particulate Matter Initiates Inflammatory Cytokine Release by Activation of Capsaicin and Acis Receptors in a Human Bronchial Epithlial Cell Line, Toxicology and Appllied Pharmacology 154, (1999) pp106-115.	
	.,	WINTER J ET AL, Capsaicin and pain mechanisms, British Journal of Anaesthesia 1995: 75: 157-168.	
		CATERINA MJ, ET AL., The capsaicin receptor: a heat-activated ion channel in the pain pathway, Nature, Vol 389 October 1997, pages, 816-824	
		TOMINAGA M ET AL., The Cloned Capsaicin Receptor Integrates Multiple Pain-Producing Stimuli, Neuron, Vol 21, pp 531-543 Sept. 1998	
	مبه	WOOD JN ET AL., Capsaicin-Induced Ion Fluxes in Dorsal Root Ganglion Cells in Culture, The Journal of Neuroscience, September 1988, 8(9): 3208-3220	
	de	BEVAN S. ET AL., Capsazepine: a competitive antagonist of the sensory neurone excitant capsaicin, Br. J Pharmacol, (1992), 107, pp 544-552	
	_	·HARVEY, JS ET AL., Activation of Protein Kinase C by the Capsaicin Analogue Resiniferatoxin in Sensory Neurones, Journal of Neurochemistry 65: 1995 1309-1317.	
	7	SZALLASI, GOSO ET AL, Competitive Inhibition by Capsazepine of [3H]Resiniferatoxin Binding to Central (Spinal Cord and Dorsal Root Ganglia) and Peripheral (Urinary Bladder and Airways) Vanilloid (Capsaicin) Receptors in the Rat, J Pharmacol Exp Ther, 267: 728-33 1993	
	e	SZALLASI & GOSO, Characterization by [3H]resiniferatoxin binding of a human vanilloid (capsaicin) receptor in post-mortem spinal cord, Neuroscience Letters, 165(1994) 101-104.	re
	1	SZALLASI A & BLUMBER PM, Specific binding of resiniferatoxin, an ultrapotent capsaicin analog, by dorsal root ganglion membranes, Brain Research, 524, (1990) 106-111	
		ACS, M PALKOVITS, BLUMBERG, [3H]Resiniferatoxin binding by the human vanilloid (capsaicin) receptor, Molecular Brain Research, 23: 185-90 1994	
		BLUMBERG ET AL., Labelled Resiniferatoxin, Compositions Thereof, and Methods for Using the Same., Filed 29 Jun 90, National Institutes of Health, Bethesda, MD. Report Nos: PAT-APPL-7-546 141 48pages.	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.